

WarmAir 135 Device Modification Special 510(k)

Special 510(k) Summary

JAN 17 2013

1. COMPANY INFORMATION

Cincinnati Sub-Zero Products, Inc.
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2. CONTACT INFORMATION

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President and CEO
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3. DATE PREPARED: December 19, 2012

4. DEVICE TRADE NAME: WarmAir® Model 135 Hyperthermia System including FilteredFlo® blankets

5. COMMON NAME: Temperature Management System

6. CLASSIFICATION NAME: System, Thermal Regulating

7. CLASSIFICATION REGULATION: 21 CFR 870.5900

8. CLASSIFICATION PRODUCT CODE: DWJ (Thermal Regulating System)

9. PANEL: Cardiovascular

10. DEVICE CLASSIFICATION: Class II No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act

11. IDENTIFICATION OF PREDICATE:

- a. WarmAir® Model 135 Hyperthermia System including blankets (K101148 and K121669)

DEVICE DESCRIPTION

The WarmAir 135 Hyperthermia System is a patient temperature management device which provides forced air warmed by the controller to a blanket that is placed over or under adult, pediatric or neonatal patients in order to warm them. The heated air is blown

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through connecting flexible hose to a disposable blanket to provide patient therapy by the means of warmed air.

The system can be used in long-term care facilities, surgical facilities, hospitals including the Post-anesthesia Care Unit (PACU), Intensive Care Unit (ICU), Surgical Intensive Care Unit (SICU), Emergency Room (ER), Operating Room (OR), recovery room, medical and surgical floors, emergency department, or any other department or hospital facility requiring patient temperature management.

DESCRIPTION OF THE CHANGES TO THE DEVICE

The predicate WarmAir Model 135 System included a variety of blankets in various sizes and shapes and was cleared in K101148. A subsequent submission K121669 added a sterile cardiac blanket to the blanket family. This submission is to add a non-sterile blanket with modified geometry to the family of WarmAir 135 FilteredFlo® blankets. The modified blanket is manufactured from the same materials using the same manufacturing methods as the already cleared blankets. The major differences are that the modified blanket differs in size from other blankets and is placed under the body of the patient in the same manner as the neonate/pediatric FilteredFlo® blanket previously cleared in K101148. There is no change to the intended use statement.

INTENDED USE

The WarmAir 135 patient warming system is intended to prevent hypothermia and/or reduce cold discomfort before, during, and after surgical procedures. The thermal regulating system is used to raise a patient's temperature and/or maintain a desired patient temperature through convective heat transfer from the controller to a warm-air-heated blanket. The single-patient use blankets transfer the thermal energy to adult, pediatric, or neonate patients to obtain/maintain normal body temperature. It is intended for use by appropriately trained healthcare professionals in clinical environments.

COMPLETION OF DESIGN CONTROL ACTIVITIES

The changes to the blanket were evaluated under design controls and met the criteria in ASTM F-2196 as did the other FilteredFlo® blankets. Testing of the blanket under a simulated patient showed the modified blanket meets the specification for maximum contact surface temperature to be within the requirements identified in ASTM F-2196.

SUBSTANTIAL EQUIVALENCE

The modified device has the same intended use as the predicates and similar technological characteristics that do not raise different types of questions of safety and effectiveness thus meeting the definition of substantial equivalence. Testing shows the modified blanket to perform similarly to the predicate blankets.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

JAN 17 2013

Cincinnati Sub-Zero Products, Inc.
Mr. Steve Berke, President and CEO
12011 Mosteller Road
Cincinnati, Ohio 45241-1528

Re: K123946

Trade/Device Name: WarmAir[®], Model 135 Hyperthermia System (Controller and Blankets)
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal regulating system
Regulatory Class: Class II
Product Code: DWJ
Dated: December 14, 2012
Received: December 21, 2012

Dear Mr. Berke,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Matthew G. Hillebrenner

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123946

Device Name: Warm Air® Model 135 and Blankets

Indications for Use:

The WarmAir® 135 patient warming system is intended to prevent hypothermia and/or reduce cold discomfort before, during, and after surgical procedures. The thermal regulating system is used to raise a patient's temperature and/or maintain a desired patient temperature through convective heat transfer from the controller to a warm-air-heated blanket. The single-patient use blankets transfer the thermal energy to adult, pediatric or neonate patients to obtain/maintain normal body temperature. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. J. Allen

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K123946

(Posted November 13, 2003)

Page 1 of 1